

510k Summary for A.) Glucose Shepherd Blood Glucose Monitoring System  
and B.) Glucose Shepherd Pro Blood Glucose Monitoring System

## 510(k) Summary

(Per 21 CFR 807.92)

### 1. Submitter Information

Company Name	BroadMaster Biotech Corporation
Address	7F, No.168-2, Liancheng Rd., Zhonghe City Taipei County 23553, Taiwan
Contact Person	Roger Lai
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Date Prepared	2010/8/13

### 2. Device Name

Proprietary Name	A.)Glucose Shepherd Blood Glucose Monitoring System and B.) Glucose Shepherd Pro Blood Glucose Monitoring System
Common Name	Blood Glucose Test System
Classification Number	System, Test, Blood Glucose, Over the Counter
Classification Panel	Chemistry
Product Code	NBW, CGA
Regulation Number	862.1345

### 3. Predicate Device

Proprietary Name	Advocate Redi-Code Blood Glucose Monitoring System
Common Name	Blood Glucose Test System
Manufacturer	Taidoc Technology Corporation
510(k) Number	k072039

### 4. Device Description

A.) Glucose Shepherd Blood Glucose Monitoring System consists of a

blood glucose meter, test strips, control solutions(Level 1, 2 and 3), lancing device, and commercially available sterilized lancets. This system utilizes amperometric method to generate a current. The size of the current is proportional to the amount of glucose presented in the sample, providing a quantitative measure of glucose level in whole blood.

B.) Glucose Shepherd Pro Blood Glucose Monitoring System consists of a blood glucose meter, test strips, control solutions(Level 1, 2 and 3) and single-use lancing devices. This system utilizes amperometric method to generate a current. The size of the current is proportional to the amount of glucose level presented in the sample, providing a quantitative measure of glucose level in whole blood.

### **Intended Use**

A.) Glucose Shepherd Blood Glucose Monitoring System is intended for use outside the body (in vitro diagnostic use) at home. It is used for quantitative measurement of glucose level in fresh capillary whole blood samples (from the finger, the palm, the forearm, the upper arm, the calf and the thigh). The alternative site testing can be only used during steady-state blood glucose monitoring. The Glucose Shepherd Blood Glucose Monitoring System is intended for use by a single person and should not be shared. In addition, it is intended for use at home as an aid in monitoring the effectiveness of diabetes control program. It should not be used for the diagnosis or screening of diabetes, nor for the testing of neonates.

The Glucose Shepherd Blood Glucose Monitoring System consists of the Glucose Shepherd Blood Glucose meter and the Glucose Shepherd Blood Glucose test strips. The Glucose Shepherd Blood Glucose meter is used only with Glucose Shepherd Blood Glucose test strips to quantitatively measure glucose in fresh capillary whole blood samples drawn from finger tips, the palm, the forearm, the upper arm, the calf and the thigh.

The Glucose Shepherd Control Solutions are for use with the Glucose Shepherd Blood Glucose Monitoring System as a quality control check to verify the accuracy of blood glucose test results.

B.) Glucose Shepherd Pro Blood Glucose Monitoring System is intended for use outside the body (in vitro diagnostic use). It is used for quantitative measurement of glucose level in fresh capillary whole blood samples (from the

finger, the palm, the forearm, the upper arm, the calf and the thigh). The alternative site testing can be only used during steady-state blood glucose monitoring. The Glucose Shepherd Pro Blood Glucose Monitoring System may be used for multiple patients in a professional healthcare setting. It is intended for use as an aid in monitoring the effectiveness of diabetes control program. This system is only used with single-use, auto-disabling lancing devices. It should not be used for the diagnosis or screening of diabetes, for the testing of neonates, or for testing of arterial blood.

The Glucose Shepherd Pro Blood Glucose Monitoring System consists of the Glucose Shepherd Pro Blood Glucose meter and the Glucose Shepherd Pro Blood Glucose test strips. The Glucose Shepherd Pro Blood Glucose meter is used only with Glucose Shepherd Pro Blood Glucose test strips to quantitatively measure glucose in fresh capillary whole blood samples drawn from finger tips, the palm, the forearm, the upper arm, the calf and the thigh.

The Glucose Shepherd Pro control solutions are for use with the Glucose Shepherd Pro Blood Glucose Monitoring System as a quality control check to verify the accuracy of blood glucose test results.

## 5. Comparison to Predicate Device

A.)

<b>Similarities</b>		
<b>Item</b>	Glucose Shepherd Blood Glucose Monitoring System (Proposed device)	Advocate Redi-Code Blood Glucose Monitoring System (Predicate device)
<b>Enzyme</b>	Glucose Oxidase	Same
<b>Measurement principle</b>	Amperometric method	Same
<b>Intended use</b>	Glucose Shepherd Blood Glucose Monitoring System is intended for use outside the body (in vitro diagnostic use) at home. It is used for quantitative measurement of glucose level in fresh capillary whole blood samples (from the	The Advocate Redi-Code Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the following alternative sites: the palm, the forearm,

	<p>finger, the palm, the forearm, the upper arm, the calf and the thigh). The alternative site testing can be only used during steady-state blood glucose monitoring. The Glucose Shepherd Blood Glucose Monitoring System is intended for use by a single person and should not be shared. In addition, it is intended for use at home as an aid in monitoring the effectiveness of diabetes control program. It should not be used for the diagnosis or screening of diabetes, nor for the testing of neonates.</p> <p>The Glucose Shepherd Blood Glucose Monitoring System consists of the Glucose Shepherd Blood Glucose meter and the Glucose Shepherd Blood Glucose test strips. The Glucose Shepherd Blood Glucose meter is used only with Glucose Shepherd Blood Glucose test strips to quantitatively measure glucose in fresh capillary whole blood samples drawn from finger tips, the palm, the forearm, the upper arm, the calf and the thigh.</p> <p>The Glucose Shepherd Control Solutions are for use with the</p>	<p>the upper-arm, the calf and the thigh. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.</p>
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	Glucose Shepherd Blood Glucose Monitoring System as a quality control check to verify the accuracy of blood glucose test results.	
<b>Sample type</b>	Fresh capillary whole blood	Same
<b>Coding</b>	No	Same
<b>Power</b>	Two 1.5V AAA alkaline batteries	Same
<b>Alternate site capability</b>	Yes	Same
<b>Hematocrit range</b>	20-60%	Same
<b>Operating condition</b>	50°F ~ 104°F (10°C ~ 40°C), below 85% R.H.	Same
<b>Strip storage condition</b>	39.2°F ~ 104°F (4°C ~ 40°C), below 85% R.H.	Same
<b>PC link</b>	Yes	Same
<b>Differences</b>		
<b>Weight</b>	53g	69.87g
<b>Dimensions</b>	64mmx95mmx29mm	96mm(L)x20mm(W)x45mm(H)
<b>Test time</b>	5 seconds	7 seconds
<b>Test volume</b>	1.1µL	0.7µL
<b>Memory</b>	400 measurements with optional before/after meal flags	450 measurements with day and time
<b>Test Range</b>	20-600 mg/dL	20-600 mg/dL
<b>Glucose units</b>	mg/dL	Either mg/dL or mmol/L
<b>Alarms</b>	6	No
<b>Pre-meal and Post-meal flags</b>	Yes	No

B.)

<b>Similarities</b>		
<b>Item</b>	Glucose Shepherd Pro Blood	Advocate Redi-Code Blood

	Glucose Monitoring System (Proposed device)	Glucose Monitoring System (Predicate device)
<b>Enzyme</b>	Glucose Oxidase	Same
<b>Measurement principle</b>	Amperometric method	Same
<b>Intended use</b>	<p>Glucose Shepherd Pro Blood Glucose Monitoring System is intended for use outside the body (in vitro diagnostic use). It is used for quantitative measurement of glucose level in fresh capillary whole blood samples (from the finger, the palm, the forearm, the upper arm, the calf and the thigh). The alternative site testing can be only used during steady-state blood glucose monitoring. The Glucose Shepherd Pro Blood Glucose Monitoring System may be used for multiple patients in a professional healthcare setting. It is intended for use as an aid in monitoring the effectiveness of diabetes control program. This system is only used with single-use, auto-disabling lancing devices. It should not be used for the diagnosis or screening of diabetes, for the testing of neonates, or for testing of arterial blood.</p> <p>The Glucose Shepherd Pro Blood Glucose Monitoring System consists of the</p>	<p>The Advocate Redi-Code Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the following alternative sites: the palm, the forearm, the upper-arm, the calf and the thigh. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.</p>

	<p>Glucose Shepherd Pro Blood Glucose meter and the Glucose Shepherd Pro Blood Glucose test strips. The Glucose Shepherd Pro Blood Glucose meter is used only with Glucose Shepherd Pro Blood Glucose test strips to quantitatively measure glucose in fresh capillary whole blood samples drawn from finger tips, the palm, the forearm, the upper arm, the calf and the thigh.</p> <p>The Glucose Shepherd Pro control solutions are for use with the Glucose Shepherd Pro Blood Glucose Monitoring System as a quality control check to verify the accuracy of blood glucose test results.</p>	
<b>Sample type</b>	Fresh capillary whole blood	Same
<b>Coding</b>	No	Same
<b>Power</b>	Two 1.5V AAA alkaline batteries	Same
<b>Alternate site capability</b>	Yes	Same
<b>Hematocrit range</b>	20-60%	Same
<b>Operating condition</b>	50°F ~ 104°F (10°C ~ 40°C), below 85% R.H.	Same
<b>Strip storage condition</b>	39.2°F ~ 104°F (4°C ~ 40°C), below 85% R.H.	Same
<b>PC link</b>	Yes	Same
<b>Differences</b>		
<b>Weight</b>	53g	69.87g

<b>Dimensions</b>	64mmx95mmx29mm	96mm(L)x20mm(W)x45mm(H)
<b>Test time</b>	5 seconds	7 seconds
<b>Test volume</b>	1.1µL	0.7µL
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<b>Test Range</b>	20-600 mg/dL	20-600 mg/dL
<b>Glucose units</b>	mg/dL	Either mg/dL or mmol/L
<b>Alarms</b>	6	No
<b>Pre-meal and Post-meal flags</b>	Yes	No

## 6. Performance Studies

A.) The performance of the Glucose Shepherd Blood Glucose Monitoring System was studied in the laboratory and in clinical settings. The studies have demonstrated that this system meets the performance requirements of its intended use.

B.) The performance of the Glucose Shepherd Pro Blood Glucose Monitoring System was studied in the laboratory and in clinical settings. The studies have demonstrated that this system meets the performance requirements of its intended use.

## 7. Conclusion

A.) The laboratory testing results, clinical testing results and labeling of Glucose Shepherd Blood Glucose Monitoring System matches the Indications for Use and support the claim of substantial equivalence to the predicate.

B.) The laboratory testing results, clinical testing results and labeling of Glucose Shepherd Pro Blood Glucose Monitoring System matches the Indications for Use and support the claim of substantial equivalence to the predicate.





BroadMaster Biotech Corporation  
c/o Roger Lai  
Regulatory Affairs Manager  
7F, No. 168-2, Liancheng Rd., Zhonghe City  
Taipei County 23553, Taiwan

Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

OCT - 7 2011

Re: k102316

Trade/Device Name: Glucose Shepherd Blood Glucose Monitoring System  
Glucose Shepherd Pro Blood Glucose Monitoring System

Regulation Number: 21 CFR 862.1345

Regulation Name: Glucose Test System

Regulatory Class: Class II, Class I, reserved

Product Code: NBW, CGA, JJX

Dated: September 28, 2011

Received: September 30, 2011

Dear Mr. Lai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

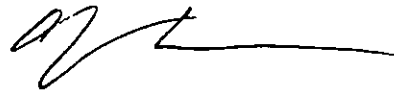
If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or ( 301 ) 796-5680 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'C. Lias', with a long horizontal flourish extending to the right.

Courtney H. Lias, Ph.D.  
Director  
Division of Chemistry and Toxicology  
Office of *In Vitro* Diagnostic Device  
Evaluation and Safety  
Center for Devices and Radiological Health

Enclosure

## Indications for Use Form

510(k) Number (if known): K102316

Device Name: Glucose Shepherd Blood Glucose Monitoring System

### Indications for Use:

Glucose Shepherd Blood Glucose Monitoring System is intended for use outside the body (in vitro diagnostic use) at home. It is used for quantitative measurement of glucose level in fresh capillary whole blood samples (from the finger, the palm, the forearm, the upper arm, the calf and the thigh). The alternative site testing can be only used during steady-state blood glucose monitoring. The Glucose Shepherd Blood Glucose Monitoring System is intended for use by a single person and should not be shared. In addition, it is intended for use at home as an aid in monitoring the effectiveness of diabetes control program. It should not be used for the diagnosis or screening of diabetes, nor for the testing of neonates.

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The Glucose Shepherd Control Solutions are for use with the Glucose Shepherd Blood Glucose Monitoring System as a quality control check to verify the accuracy of blood glucose test results.

Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use  X   
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)



Division Sign-Off  
Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k) K102316

## Indications for Use Form

510(k) Number (if known): K102316

Device Name: Glucose Shepherd Pro Blood Glucose Monitoring System

### Indications for Use:

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The Glucose Shepherd Pro control solutions are for use with the Glucose Shepherd Pro Blood Glucose Monitoring System as a quality control check to verify the accuracy of blood glucose test results.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use   X    
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)



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